REMARKS

Claims 1, 3, 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman (U.S. Patent No. 6,251,064) [Silverman I] in view of Astarita (U.S. Patent No. 6,228,059) in further view of Silverman et al. (U.S. Patent No. 6,251,063) [Silverman II]. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman I in view of Astarita in view of Silverman II as applied to Claim 3, and further in view of Kikawada (U.S. Patent No. 5,637,075). Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman I in view of Astarita in view of Silverman II as applied to Claim 1, and further in view of Morrison (U.S. Patent No. 4,609,370). Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman I in view of Silverman II.

Silverman I discloses a method for creating valve-like mechanism in natural body passageway. In particular, Silverman I discloses that a suitable apparatus or medical device 41 includes a probe member or probe 42 having an optical viewing device. A conventional or other suitable gastroscope or endoscope can be used for probe 42. An exemplary probe is an Olympus CF Type 40L/I endoscope made by Olympus Corporation of Tokyo, Japan. A needle assembly 43 is slidably carried by probe 42. Needle assembly 43 can be of any conventional type, such as a modified sclerotherapy needle similar to the Bard.RTM. Flexitip.TM. needle manufactured by C. R. Bard, Inc. of Billerica, Md., and includes a needle member or needle 44 and protective sleeve 46. Device 41 further includes a supply assembly (not shown) mounted to the proximal end portion of needle assembly 43. Column 2, lines 55-67.

Silverman II discloses a method for treating wall forming gastrointestinal tract. Specifically, Silverman II discloses that the method can be performed with an apparatus of the type shown in FIG. 1. Apparatus or medical device 21 shown therein includes a probe member or probe 22 having an optical viewing device 23. A needle assembly 26 is slidably carried by probe 22. Column 4, lines 10-14. A conventional or other suitable gastroscope or endoscope can be used for probe 22. The exemplary probe 22 shown in FIG. 1 is an Olympus CF Type 40L/I endoscope made by Olympus Corporation of Tokyo Japan. Probe 22 includes a flexible elongate tubular member or insertion tube 31 having proximal and distal extremities 31a and 31b and a distal face 32. Column 4, lines 17-23. A working passageway or channel 51 is further provided in insertion tube 31 and extends to a side port 52 formed in handle 33. Column 4, lines 47-49. Needle assembly 26 can be of any conventional type such as a modified sclerotherapy needle

similar to the Bard.RTM. Flexitip.TM. needle manufactured by C. R. Bard, Inc. of Billerica, Md. Needle assembly 26 includes a needle member or needle 61 having a proximal end portion 61a and a distal end portion 61b and an optional sleeve member or sleeve 62 having a proximal end portion or extremity 62a and a distal end portion or extremity 62b. Sleeve or elongate tubular member 62 is made from any suitable material such as flexible plastic or metal and has a lumen extending longitudinally therethrough for receiving the needle 61. The sleeve 62 and the needle 61 are slidable relative to each other in a longitudinal direction. Needle 61 and sleeve 62 can be slidably disposed within working channel 51 and side port 52 of insertion tube 31 and each have a length so that when distal end portions 61b and 62b are extending from distal extremity 31b of the insertion tube 31 or otherwise in the vicinity of distal face 32, proximal end portions 61a and 62a are accessible at side port 52. Column 4, line 59 – Column 5, line 15.

Astarita discloses a locking device for use in a trocar inserted into a body cavity. The locking device include various operating components that may be easily manipulated and recognized by a surgeon during complicated surgery, and a locking portion secured in the trocar. The locking portion may include internal threads formed only on a head, a cam operated element, resilient fingers, a collet-type locking device, or a frictional detent or opening, quickly moved into a locking position against any type of instrument passing through the trocar into the body cavity. The portion of the locking device contacting the instrument must be sized and dimensioned to provide a firm grip in the locking position, without damaging or marring the instrument against which it is locked. See Abstract.

Claim 1 is patentable by calling for an injection device for use with a probe of the type set forth therein including a first tubular member adapted for use with the probe and having a diameter for permitting insertion into the passageway of the probe, a second tubular member slidably disposed in the first tubular member, and means carried by the proximal extremities of the first and second tubular members for locking the proximal extremity of the second tubular member relative to the proximal extremity of the first tubular member, the second tubular member having a column strength when locked within the first tubular member so as not to buckle during puncture of the tissue by the needle and thus limit retraction of the second tubular member relative to the first tubular member during puncture of the tissue and provide substantially one-to-one movement between the proximal and distal extremities of the second tubular member.

Contrary to the statement of the Examiner, reference number 42 in Silverman I does not refer to a first tubular member having a diameter for permitting insertion into the passageway of a probe as called for in Claim 1 but instead, as discussed above, refers to a probe. Silverman II, as discussed above, also discloses a probe 22. There is no suggestion in Silverman I or Silverman II, or in Astarita for that matter, that probe 42 of Silverman I could be modified as suggested by the Examiner for use in probe 22 of Silverman II.

In addition to the foregoing, and again contrary to the assertions of the Examiner, none of Silverman I, Silverman II and Astarita, alone or in combination, disclose an injection device of the type called for in Claim 1, and in particular an injection device in which the second tubular member has a column strength when locked within the first tubular member so as not to buckle during puncture of the tissue by the needle and thus limit retraction of the second tubular member relative to the first tubular member during puncture of the tissue and provide substantially one-to-one movement between the proximal and distal extremities of the second tubular member.

The Examiner acknowledges that Silverman is silent on the column strength of the second tubular member, but argues that "since the needle punctures the tissue it is clear that the tubular member has the strength not to buckle or else the device would be useless." Office Action, pg. 5, paragraph 9. Since it is unclear as to which Silverman reference the Examiner relies upon in support of his position on column strength, it is difficult for Applicant to specifically address the Examiner's concerns. Regardless, neither Silverman I nor Silverman II disclose an injection device as called for in Claim 1.

Silverman I, Silverman II, and Astarita are each silent with regard to the second tubular member having a column strength when locked within the first tubular member so as not to buckle during puncture of the tissue by the needle and thus limit retraction of the second tubular member relative to the first tubular member during puncture of the tissue, which is a significant improvement in facilitating the accuracy of placement of the needle in the tissue. In fact, contrary to the Examiner's assertions, the devices disclosed in Silverman I and Silverman II would not be "useless" as suggested by the Examiner if the second tubular member thereof, for example needle 44 of Silverman I, buckled with the first tubular member thereof, for example sleeve 46 of Silverman I, since, for example with respect to Silverman I, needle 44 is at least partially supported against buckling by sleeve 46 and by probe 42. Accordingly, due to the

general physical composition and nature of a needle, it is likely that such a need can be inserted into tissue by the application of force. However, the accuracy of placement of the needle is hindered to the extent buckling is not restricted. In this regard, it is stated in the "Background" portion of the present application at Page 1, lines 14-17:

> Medical devices have been provided for the delivery of an implant-forming material to various portions of the wall forming a vessel such as the gastrointestinal tract of a mammalian body. See, for example, U.S. Patent No. 6,251,063 [Silverman II]. There remains, however, a need for increased accuracy in the placement of such material and the implants formed thereby.

Increasing the accuracy in placing implants is an important feature of the invention. As discussed in the disclosure of the present application, enhancing the placement accuracy of the needle serves to inhibit damage to the mucosal layer and other adjacent muscle layers from improperly placed material. Page 17, lines 13-15. Specifically, the limiting of the longitudinal travel or retraction of needle, which is carried by the second tubular member, relative to first tubular member permits greater accuracy in the placement depth of the needle in the targeted tissue, thus facilitating relatively consistent puncture depths between injection sites. See Page 20, lines 24-26. Since contraction has been limited, as claimed, by the increased column strength of the second tubular member when locked within the first tubular member, the amount of advancement of needle into the probe translates essentially one-to-one with the amount that needle is advanced into the tissue. See Page 20, lines 29-33. Such an improvement is not shown in Silverman I, Silverman II, or Astarita.

Claims 2-11 depend from Claim 1 and are patentable for the same reasons as Claim 1, and by reason of the additional features called for therein.

Claim 12 is patentable by calling for an injection device of the type set forth therein, and in particular an injection device having a first tubular member adapted for use with the probe and having a diameter for permitting insertion of the first tubular member into the passageway of the probe, the first tubular member having a proximal extremity with a proximal opening and a distal extremity, a second tubular member extending through the proximal opening of the first tubular member and being slidably disposed in a lumen of the first tubular member and having a distal extremity with a needle that is extendable from the distal extremity of the first tubular member, the proximal extremity of the first tubular member having a port distal of the proximal opening, a

reservoir of the biocompatible solvent coupled to the port for clearing any of the biocompatible composition that clogs the first tubular member distal of the port.

It appears that the Examiner is mixing up Silverman I and Silverman II is his rejection of Claim 12 and thus it is difficult for Applicant to understand such rejection. Nonetheless, and contrary to any assertion of the Examiner, there is no suggestion in either Silverman I or Silverman II "to modify the device of Silverman I to have the tubular members sized to fit in the lumen of a probe and a port distal of the proximal opening as taught by Silverman II so that a noninvasive procedure can be performed." More specifically, there is no suggestion in Silverman I or Silverman II that probe 42 of Silverman I could be modified for use in probe 22 of Silverman II or that probe 22 of Silverman II could be modified for use in probe 42 of Silverman I. Furthermore, even if Silverman I and Silverman II are combined as suggested by the Examiner, neither of such references disclose a reservoir of a biocompatible solvent coupled to a port, let alone a reservoir of a biocompatible solvent coupled to a port for clearing any of the biocompatible composition that clogs the first tubular member, having a second tubular member slidably disposed therein, distal of the port.

The ability to clear the first tubular member of any of the biocompatible composition that clogs the first tubular member is an important feature of the invention. As indicated in the Detailed Description of the Application, in the step of forming an implant in a wall of one embodiment, a solution of biocompatible polymer and a solution of biocompatible solvent are combined and a biocompatible polymer precipitates from the solution so that the biocompatible polymer solidifies in the wall. Should any of the biocompatible polymer in the nonaqueous solution solidify or precipitate within the injection device, such material may effectively plug the first tubular member so that the second tubular member may not be deployed from the first tubular member distal opening. In order to clear the first tubular member for use, a biocompatible solvent can be introduced under pressure to redissolve the biocompatible polymer at the point of precipitation and thus clear the first tubular member for use.

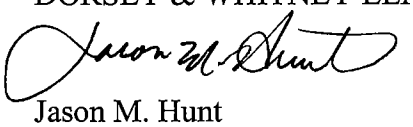
Claims 13-15 depend from Claim 12 and are patentable for the same reasons as claim 12 and by reason of the additional features called for therein.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that the application is not in a condition for allowance and that a telephone interview would help

further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

DORSEY & WHITNEY LLP



Jason M. Hunt
Reg. No. 53,048

Customer No. 32,940
555 California Street, Suite 1000
San Francisco, CA 94104-1513
Telephone No.: (650) 857-1717
Facsimile No.: (650) 857-1288

4815-9748-3777\1